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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/622,207

07/18/2003

Edwin J. Hlavka

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/622,207	<b>Applicant(s)</b> HLAVKA ET AL.	
	<b>Examiner</b> William H. Matthews (Howie)	<b>Art Unit</b> 3774	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 60-67 and 69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 60-67 and 69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 60-67 and 69 have been considered but are not persuasive. Applicant contend Kuehn et al. do not anticipate claim 60 because Kuehn et al fail to disclose a tensioning element coupled to the fasteners and configured to be tensioned by pulling on only one end thereof. Examiner disagrees because paragraph [0090] clearly disclose a variation meeting this limitation. Applicant further argues that the fasteners of Kuehn do not meet the claim limitations because they are fastened to the leaflets. Examiner disagree because the structural requirements of the fasteners are not determined by the exact placement, or intended use, of the fasteners.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 69 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "T-bar" is not sufficiently described in the specification nor shown in figures so as to ascertain the meaning of the limitation.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3774

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 60-67, and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuehn et al. US PUB 2004/0167539.

4. Kuehn et al. disclose in paragraphs 76-78,87-90,120 and figures 8-11 a device for use in annuloplasty procedures comprising plurality of non-plicating fasteners, catheter having guidewire, elongate tensioning element connecting the fasteners having a locking knot feature, and expandable members ("jaws") capable of being expanded against tissue. As best understood, the "T-bar" limitation is met by the barbed needles shown in figures 8, 11, and 12.

5. Claims 60-62,65,67 are rejected under 35 U.S.C. 102(e) as being anticipated by Solem et al. US PUB 2001/0018611.

6. Solem et al. disclose in figures 12-17 a device for use in catheter based annuloplasty comprising a plurality of non-plicating fasteners (anchors 23,24,25,30,31), catheter (paragraph 70), elongate tensioning elements (26,27,35,36,37,38,39,40), and locking feature operative to fix the fasteners in a closer, or activated, state.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 63,64,69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. US PUB 2001/0018611 as applied to claims 60-62,65,67 above, and further in view of Kuehn et al. USPN 2004/0167539.

7. Solem et al. is described supra, but further teach the use of anchors as shown in figures 2-7. Solem et al. lack the express written disclosure of using a knot to lock the tensioning element as well as the fasteners comprising T-bar anchors. Kuehn et al. teach in figures 8,11, and 12 T-bar anchors 222 for securely fixing a device to tissue and the technique of using knots to secure a tensioned element at the desired tension (paragraph 90) for annuloplasty repair. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Solem et al. to include the T-bars to the fasteners and knot technique, as taught by Kuehn et al., in order to enhance the fixation to tissue and to lock the desired tension.

Claims 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. US PUB 2001/0018611.

8. Solem et al. is described supra. With regard to claim 66, Solem et al. lack the express written disclosure of using an expandable member (such as a balloon). However, Solem do disclose the use of conventional catheter techniques to expand the anchors of figures 12-17 (see paragraph 70). Examiner hereby take Official Notice that conventional catheter techniques are well known in the art to include balloon expansion members for expanding anchors as disclosed in Solem. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device

disclosed by Solem et al. to include an expandable balloon member in order to expand the anchors.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/  
Primary Examiner  
Art Unit 3774

Application/Control Number: 10/622,207  
Art Unit: 3774

Page 6